



# STANDARDS AND CONFORMITY ASSESSMENT

## Excerpt From Country Commercial Guide

Trade.gov/standards

### Standards and Conformity Assessment in the European Union

#### Overview

Products tested and certified in the United States to American standards are likely to have to be retested and re-certified to EU requirements as a result of the EU's different approach to the protection of the health and safety of consumers and the environment. Where products are not regulated by specific EU technical legislation, they are always subject to the EU's General Product Safety Directive (see section 4.4) as well as to possible additional national requirements.

European Union standards created in recent years under the New Approach are harmonized across the 25 EU Member States and European Economic Area countries to allow for the free flow of goods. A feature of the New Approach is CE marking. While harmonization of EU legislation can facilitate access to the EU Single Market, manufacturers should be aware that regulations and technical standards might also become barriers to trade if U.S. standards are different from those of the European Union.

#### Agricultural Standards

The establishment of harmonized EU rules and standards in the food sector has been ongoing for several decades, but it took until January 2002 for the publication of a general food law establishing the general principles of EU food law. This regulation introduced mandatory traceability throughout the feed and food chain as of Jan 1, 2005. For specific information on agricultural standards, please refer to the Foreign Agricultural Service's website at: <http://www.useu.be/agri/usda.html>.

#### Standards Organizations

EU standards setting is a process based on consensus initiated by industry or mandated by the European Commission and carried out by independent standards bodies, acting at the national, European or international level. There is strong encouragement for nongovernmental organizations, such as environmental and consumer groups, to actively participate in European standardization. Many standards in the EU are adopted from international standards bodies such as the International Standards Organization (ISO). The drafting of specific EU standards is handled by three European standards organizations:

- CENELEC, European Committee for Electrotechnical Standardization (<http://www.cenelec.org/>)
- ETSI, European Telecommunications Standards Institute (<http://www.etsi.org/>)
- CEN, European Committee for Standardization, handling all other standards (<http://www.cenorm.be/>)



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Standards are created or modified by experts in Technical Committees or Working Groups. The members of CEN and CENELEC are the national standards bodies of the Member States, which have "mirror committees" that monitor and participate in ongoing European standardization. CEN and CENELEC standards are sold by the individual Member States standards bodies as well as through the American National Standards Institute (ANSI) <http://www.ansi.org/>. ETSI is different in that it allows direct participation in its technical committees from non-EU companies that have interests in Europe and gives away its individual standards at no charge on its website. In addition to the three standards developing organizations, the European Commission plays an important role in standardization through its funding of the participation in the standardization process of small- and medium-sized companies and non-governmental organizations, such as environmental and consumer groups. The Commission also provides money to the standards bodies when it mandates standards development to the European Standards Organization for harmonized standards that will be linked to EU technical regulations. All EU harmonized standards, which provide the basis for CE marking, can be found on <http://www.newapproach.org/>.

Due to the EU's vigorous promotion of its regulatory and standards system as well as its generous funding for its business development, the EU's standards regime is wide and deep - extending well beyond the EU's political borders to include affiliate members (countries which are hopeful of becoming full members in the future) such as Albania, Bulgaria, Croatia, Romania, FYR of Macedonia, and Turkey. Another category, called "partner standardization bodies" includes the standards organizations of South Africa, Egypt, Serbia-Montenegro and Ukraine, which are not likely to join the EU or CEN any time soon, but have an interest in participating in specific CEN technical committees. They agree to pay a fee for full participation in certain technical committees and agree to implement the committee's adopted standards as national standards. Many developing countries such as the Mediterranean and Balkan countries, some Latin American countries, China, and Russia receive EU technical assistance aimed at encouraging adoption of EU standards and technical regulations.

To know what CEN and CENELEC have in the pipeline for future standardization, it is best to visit their websites. CEN's "business domain" page provides an overview by sector and/or technical committee whereas CENELEC offers the possibility to search its database. ETSI's portal ([http://portal.etsi.org/Portal\\_Common/home.asp](http://portal.etsi.org/Portal_Common/home.asp)) leads to ongoing activities.



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With the need to adapt more quickly to market needs, European standards organizations have been looking for "new deliverables" which are standard-like products delivered in a shorter timeframe. While few of these "new deliverables" have been linked to EU regulations, expectations are that they will eventually serve as the basis for EU-wide standards.

Key Link: <http://www.cenorm.be/cenorm/workarea/sectorfora/index.asp>.

### Conformity Assessment

Conformity Assessment is a mandatory step for the manufacturer in the process of complying with specific EU legislation. The purpose of conformity assessment is to ensure consistency of compliance during all stages of the production process to facilitate acceptance of the final product. EU product legislation gives manufacturers some choice with regard to conformity assessment, depending on the level of risk involved in the use of their product. These range from self-certification, type examination and production quality control system, to full quality assurance system. You can find conformity assessment bodies in individual Member State country in this list by the European Commission.

Key Link: <http://europa.eu.int/comm/enterprise/nando-is/home/index.cfm>.

To promote market acceptance of the final product, there are a number of voluntary conformity assessment programs. CEN's certification systems are the Keymark, the CENCER mark, and the European Standard Agreement Group. CENELEC has its own initiative. ETSI does not offer conformity assessment services.

### Product Certification

To sell products on the EU market of 25 Member States as well as Norway, Liechtenstein and Iceland, U.S. exporters are required to apply CE marking whenever their product is covered by specific product legislation. CE marking product legislation offers manufacturers a number of choices and requires decisions to determine which safety/health concerns need to be addressed, which conformity assessment module is best suited to the manufacturing process, and whether or not to use EU-wide harmonized standards. There is no easy way for U.S. exporters to understand and go through the process of CE marking, but hopefully this section provides some background and clarification.

In the eighties, the New Approach was launched to overcome the lengthy adoption process of "old approach" type legislation. The goal of the EU's harmonization program under the New Approach is to streamline technical harmonization and the development of standards for certain product groups, including, among others, machinery, toys,



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construction products, electromagnetic compatibility, personal protective equipment, non-automatic weighing instruments, medical devices, gas appliances, hot water boilers, and radio and telecommunications terminal equipment (RTTE). Under the New Approach, directives cover essential safety, health and environmental requirements. The three regional European standards organizations, CEN, CENELEC and ETSI, are mandated by the Commission to develop technical standards that are consistent with the essential requirements of EU directives.

Products manufactured to standards adopted by CEN, CENELEC and ETSI, and published in the Official Journal as harmonized standards, are presumed to conform to the requirements of EU directives. The manufacturer then applies the CE mark and issues a declaration of conformity. With these, the product will be allowed to circulate freely within the EU. A manufacturer can choose not to use the harmonized EU standards, but then must demonstrate that the product meets the essential safety and performance requirements. Trade barriers occur when design, rather than performance, standards are developed by the relevant European standardization organization, and when U.S. companies do not have access to the standardization process through a European presence.

The CE mark addresses itself primarily to the national control authorities of the Member States, and its use simplifies the task of essential market surveillance of regulated products. Although CE marking is intended primarily for inspection purposes by Member State inspectors, the consumer may well perceive it as a quality mark. The CE mark is not intended to include detailed technical information on the product, but there must be enough information to enable the inspector to trace the product back to the manufacturer or the authorized representative established in the EU. This detailed information should not appear next to the CE mark, but rather on the declaration of conformity, the certificate of conformity (which the manufacturer or authorized agent must be able to provide at any time, together with the product's technical file), or the documents accompanying the product.

### **Accreditation**

The independent certification bodies, known as notified bodies, have been officially accredited by competent authorities to test and certify to EU requirements. However, under U.S.-EU Mutual Recognition Agreements (MRAs), notified bodies based in the United States and referred to as conformity assessment bodies, are allowed to test in the United States to EU specifications, and vice versa. The costs are significantly lower which results in U.S. products becoming more competitive. At this time, the U.S.-EU MRAs cover the following sectors: EMC (in force), RTTE (in force), medical devices (in transition), pharmaceutical (in transition), and recreational craft (in force). The U.S. Department of Commerce, National Institute of Standards and Technology (NIST), has a link on its website to American and European Conformity Assessment bodies operating



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under a mutual recognition agreement.

Key Link: <http://ts.nist.gov/ts/htdocs/210/gsig/mra.htm>.

Accreditation is handled at Member State level. "European Accreditation" (<http://www.european-accreditation.org/>) is an organization representing nationally recognized accreditation bodies. Membership is open to nationally recognized accreditation bodies in countries in the European geographical area that can demonstrate that they operate an accreditation system compatible with EN45003 or ISO/IEC Guide 58.

### Publication of Technical Regulations

The Official Journal is the official gazette of the European Union. It is published daily and consists of two series covering draft and adopted legislation as well as case law, questions from the European Parliament, studies by committees, and more (<http://europa.eu.int/eur-lex/en/index.html>). It lists the standards reference numbers linked to legislation (<http://www.newapproach.org/Directives/DirectiveList.asp>). National technical regulations are published on the Commission's website <http://europa.eu.int/comm/enterprise/tris/> to allow other countries and interested parties to comment.

### Labelling and Marking

Manufacturers should be mindful that, in addition to the EU's mandatory and voluntary schemes, national voluntary labeling schemes might still apply. These schemes may be highly appreciated by consumers, and thus, become unavoidable for marketing purposes.

Manufacturers are advised to take note that all labels require metric units although dual labeling is also acceptable until end of December 2009. The use of language on labels has been the subject of a Commission Communication, which encourages multilingual information, while preserving the right of Member States to require the use of language of the country of consumption.

Council Directive 80/232/EC provides standardized ranges of nominal quantities, container capacities and volumes for a variety of products. Package sizes that were previously marketed in the EU may still be used.

Key Link: [http://europa.eu.int/eur-lex/en/consleg/main/1980/en\\_1980L0232\\_index.html](http://europa.eu.int/eur-lex/en/consleg/main/1980/en_1980L0232_index.html)





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### **The Eco-label**

The EU adopted legislation in 1992, revised in 2000, to distinguish environmentally friendly production through a voluntary labeling scheme called the Eco-label. The symbol, a green flower, is a voluntary mark, awarded to producers who can show that their product is less harmful to the environment than similar products. This "green label" aims to encourage consumers to buy environmentally friendly products.

The Eco-label is a costly scheme (up to €1,300 for registration and up to €25,000/ year for the use of the label, with a reduction of 25 percent for SMEs) and has therefore not been widely used so far. However, the Eco-label can be a good marketing tool and, given the growing demand for green products in Europe, it is possible that the Eco-label will become a reference for green consumers.

Key Links: [http://europa.eu.int/comm/environment/ecolabel/index\\_en.htm](http://europa.eu.int/comm/environment/ecolabel/index_en.htm)  
<http://www.eco-label.com>

### **Trade Agreements**

Please see EU Member State Country Commercial Guides which can be found at the following website: <http://www.export.gov/marketresearch.html> under Country and Industry Market Reports.

### **Web Resources**

<http://www.ustr.gov/> Office of the U.S. Trade Representative  
<http://www.useu.be/> U.S. Mission to the EU (USEU) website  
<http://www.useu.be/agri/usda.html> Foreign Agricultural Service website, USEU  
<http://www.ams.usda.gov/lsg/arc/audit.htm> USDA Audit, Review & Compliance  
<http://europa.eu.int/scadplus/leg/en/lvb/f81001.htm>  
EC Regulation on animal by-products  
[http://europa.eu.int/comm/taxation\\_customs/common/databases/taric/index\\_en.htm](http://europa.eu.int/comm/taxation_customs/common/databases/taric/index_en.htm)  
EC's TARIC – online customs tariff database  
<http://www.useu.be/agri/certification.html> EC Certification of Animal Products  
<http://www.nmfs.noaa.gov/trade/> National Marine Fisheries Service's Trade & Commercial Services website  
<http://www.cfsan.fda.gov/> USDA Center for Food Safety and Applied Nutrition  
[http://europa.eu.int/comm/taxation\\_customs/customs/index\\_en.htm](http://europa.eu.int/comm/taxation_customs/customs/index_en.htm)  
EC Taxation and Customs Union  
<http://www.useu.be/agri/estab.html> EU-approved U.S. Establishments  
<http://www.useu.be/agri/Fruit-Veg.html> EU Marketing Standards for Fruits & Vegetables  
<http://www.ams.usda.gov/lsg/arc/nhtc.htm> Non-Hormone Treated Cattle (NHTC) Program  
<http://www.useu.be/agri/organic.html> Organic Foods Legislation



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<http://www.cenelec.org/> CENELEC, European Committee for Electrotechnical Standardization  
<http://www.etsi.org/> ETSI, European Telecommunications Standards Institute  
<http://www.cenorm.be/> CEN, European Committee for Standardization  
<http://www.ansi.org/> ANSI, American National Standards Institute  
<http://www.newapproach.org/> New Approach Standardisation in the Internal Market  
[http://portal.etsi.org/Portal\\_Common/home.asp](http://portal.etsi.org/Portal_Common/home.asp)  
ETSI's e-Standardization portal  
<http://www.cenorm.be/cenorm/workarea/sectorfora/index.asp>  
Advisory and coordinating bodies to CEN  
<http://europa.eu.int/comm/enterprise/nando-is/home/index.cfm>  
Conformity assessment bodies in the EU and member states  
<http://ts.nist.gov/ts/htdocs/210/gsig/mra.htm>  
Government-to-Government Mutual Recognition Agreement Information  
<http://www.european-accreditation.org/> European co-operation for Accreditation  
<http://europa.eu.int/eur-lex/en/index.html> European Union law portal  
<http://www.newapproach.org/Directives/DirectiveList.asp>  
List of EU Directives and Standards  
<http://europa.eu.int/comm/enterprise/tris/> EC Technical Regulations Information System  
[http://europa.eu.int/eur-lex/en/consleg/main/1980/en\\_1980L0232\\_index.html](http://europa.eu.int/eur-lex/en/consleg/main/1980/en_1980L0232_index.html)  
EC Directive on packaging  
[http://europa.eu.int/comm/environment/ecolabel/index\\_en.htm](http://europa.eu.int/comm/environment/ecolabel/index_en.htm)  
EU Eco-label Homepage  
<http://www.eco-label.com/> European Eco-label Catalogue  
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